This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results
Roxadustat

November 16, 2022

Non-proprietary name

Roxadustat

Brand name (marketing authorization holder)

Evrenzo Tablets 20 mg, 50 mg, 100 mg (Astellas Pharma Inc.)

Indications

Nephrogenic anaemia

Summary of revisions

1. A precautionary statement on encouraging periodic thyroid function tests (measurement of thyroid-stimulating hormone (TSH), free T3, free T4) should be added to the IMPORTANT PRECAUTIONS section.
2. “Central hypothyroidism” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving hypothyroidism reported in Japan were evaluated. Cases for which a causal relationship between roxadustat and central hypothyroidism was reasonably possible have been reported in Japan. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

Number of cases and patient mortalities of unexpected hypothyroidism reported in Japan* during the previous 3 fiscal years

A total of 29 cases have been reported in Japan to date (including 9 cases for which a causal relationship between the drug and event was reasonably possible). (All the cases

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

were central hypothyroidism.)
No patient mortalities have been reported to date.
(Japanese market launch: November 2019)

* Among the cases with TSH and free T4 values as well as relevant clinical findings (refer to Guidelines for the diagnosis of thyroid disease 2021), those considered to have resulted in the equivalent of grade 3 hypothyroidism in the Common Terminology Criteria for Adverse Events (CTCAE) v5.0

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp